



IN THE CLAIMS:

Please replace claims 1-27, 29, 32-34, 36-38, 45-47 and 49-52 with the amended versions below:

1. (Amended) A method for producing a vaccine delivery system comprising a plurality of polymer particles, wherein a water insoluble protein antigen is incorporated with the polymer particles, the polymer particles comprising a matrix polymer, wherein the method comprises:

Bb (a) mixing an aqueous phase (W) comprising the water insoluble protein and one or more solubilizing agents with an organic phase (O) that is immiscible with W to produce a W/O emulsion, the O phase comprising the matrix polymer in an organic solvent;

Sub D1 (b) forming droplets of said W/O emulsion by dispersing the emulsion in a fluid medium, and removing said solvent from the O phase of the W/O emulsion droplets to thereby form the polymer particles incorporating the water insoluble protein antigen; and

wherein in step (a) one or more stabilizing agents are provided in the W/O emulsion to stabilize the W/O emulsion in the presence of the solubilizing agent and promote the incorporation of the water insoluble protein within the polymer particles during step (b).

2. (Amended) The method of claim 1, wherein more than one stabilizing agent is included in the W/O emulsion.

3. (Amended) The method of claim 1 or 2, wherein the one or more stabilizing agents is/are selected from the group consisting of polymers, polar lipids, and hydrophobic surfactants.

4. (Amended) The method of claim 3, wherein the one or more stabilizing agents is/are a polymer selected from the group consisting of poly(vinyl pyrrolidone), poly(vinyl alcohol), polysaccharides, polyethyleneoxide and water soluble proteins.

5. (Amended) The method of claim 3, wherein the one or more stabilizing agents is/are a polar lipid selected from the group consisting of cholesterol, phosphatidylcholine, phosphatidylethanolamine, phosphatidylglycerol, glycolipids and phosphatidic acid.

6. (Amended) The method of claim 3, wherein the one or more stabilizing agents is/are a non-ionic, hydrophobic surfactant selected from the group consisting of a sorbitan fatty acid ester, hydrophobic polyoxyethylene alkyl ether, sucrose ester, alkyl-glucopyranoside, polyglycerol polyricinoleate and block-copolymers of ethylene oxide with propyleneoxide and/or lactic acid.

7. (Amended) The method of claim 3, wherein the one or more stabilizing agents is/are an anionic, hydrophobic surfactant selected from the group consisting of an alkylsulphate salt, a dialkylsulphosuccinate salt, an alkylbenzene sulphonate salt and a fatty acid salt.

8. (Amended) The method of claim 3, wherein the one or more stabilizing agents is/are a cationic, hydrophobic surfactant selected from the group consisting of an alkyltrimethylammonium salt and a dialkyldimethylammonium salt.

9. (Amended) The method of claim 2, wherein one of the stabilizing agents is a sorbitan fatty acid ester.

10. (Amended) The method of claim 2, wherein the stabilizing agents comprise poly (vinyl pyrrolidone) and sodium 1, 4-bis(2-ethylhexyl) sulphosuccinate.

11. (Amended) The method of claim 1, wherein the aqueous phase comprises more than one solubilizing agent.

12. (Amended) The method of claim 1, wherein the one or more solubilizing agents is/are a hydrophilic surfactant.

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13. (Amended) The method of claim 12, wherein the hydrophilic surfactant is a non-ionic surfactant selected from the group consisting of alkyl-glucopyranosides, alkyl-thioglucopyranosides, alkyl-maltosides, alkoyl-methyl glucamides, glucamides, polyoxyethylene alcohols, polyoxyethylene alkyl phenols, emulphogens, polyoxyethylene sorbitol esters, polyoxyethylene fatty acid esters, hydrophilic polyoxyethylene alkyl ethers and digitonin.

14. (Amended) The method of claim 12, wherein the hydrophilic surfactant is an anionic surfactant selected from the group consisting of cholates, alkylsulphonates, deoxycholates, alkylsulphates, oligooxyethylene dodecyl ether sulphates and sodium dodecylsarcosinate.

15. (Amended) The method of claim 12, wherein the hydrophilic surfactant is a cationic surfactant selected from the group consisting of alkylpyridinium salts and alkyltrimethylammonium salts.

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16. (Amended) The method of claim 12, wherein the hydrophilic surfactant is a zwitterionic surfactant selected from the group consisting of (3-1-propanesulphonate) (CHAPS), (3-[(3-cholamidopropyl)-dimethylammonio]-2-hydroxy-1-propanesulphonate) (CHAPSO), (N,N-bis-cholamide) (BIGCHAP), (N,N-bis-deoxycholamide) (deoxy BIGCHAP), lyso phosphatidylcholine, alkylbetaines and sulphobetaines.

17. (Amended) The method of claim 1, wherein the one or more solubilizing agents is/are a chaotropic agent.

18. (Amended) The method of claim 17, wherein the chaotropic agent is selected from the group consisting of a perchlorate, thiocyanate, guanidine, chlorate, iodide, bromide, nitrate and urea.

19. (Amended) The method of claim 1, wherein the method is a Double Emulsion (W/O/X) Solvent Evaporation Technique and in step (b) the stabilized W/O emulsion is dispersed in a liquid phase (X) which is immiscible with the O phase to produce a W/O/X double emulsion comprising W/O droplets from which the solvent is evaporated.

20. (Amended) The method of claim 1, wherein the method is a Double Emulsion (W/O/X) Solvent Extraction Technique and in step (b) the stabilized W/O emulsion is dispersed in a liquid phase (X) which is immiscible with the O phase to produce a W/O/X double emulsion comprising W/O droplets, wherein the X phase extracts said solvent from the O phase of the droplets.

21. (Amended) The method of claim 19 or 20, wherein the X phase comprises a stabilizing agent.

22. (Amended) The method of claim 21, wherein the one or more stabilizing agents is/are selected from group consisting of polymers, polar lipids, and hydrophobic surfactants.

23. (Amended) The method of claim 1, wherein the method is a spray drying technique, and in step (b) the stabilized W/O emulsion is dispersed in a gaseous medium to form a spray of W/O emulsion droplets from which said solvent evaporates.

24. (Amended) The method of claim 1, wherein step (b) comprises a fluid gas technique to form the polymer particles.

25. (Amended) The method of claim 24, wherein the fluid gas technique is selected from the group consisting of gas anti-solvent precipitation (GAS), solution enhanced dispersion by supercritical fluid (SEDS), precipitation with compressed anti-solvents (PCA), supercritical anti-solvent (SAS) and aerosol solvent extraction system (ASES).

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26. (Amended) The method of claim 1, wherein the protein antigen is a *Helicobacter* protein or *Helicobacter* protein fragment.

27. (Amended) The method of claim 26, wherein the *Helicobacter* protein or *Helicobacter* protein fragment is from *Helicobacter pylori*.

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29. (Amended) The method of claim 28, wherein the *Helicobacter* protein is a lipidated form of *Helicobacter pylori* adhesion antigen (HpaA).

32. (Amended) The method of claim 1, wherein the matrix polymer is a homo-or co-polymer selected from one or more of the group consisting of polyesters, polyanhydrides, polyorthoesters, polycarbonates, polyamides, poly(amino acids), polyacetals, polycyanoacrylates, polyacrylates, biodegradable polyurethanes, non-erodable polyurethanes, polymers of ethylene-vinyl acetate, acyl substituted cellulose acetates, polysaccharides, polystyrenes, polyvinyl chloride, polyvinyl fluoride, poly(vinyl imidazole), chlorosulphonated polyolefins, polyethylene oxide, polyethers and polyoxalates.

33. (Amended) The method of claim 32, wherein the matrix polymer is a polyester homopolymer selected from the group consisting of polylactic acid, polyglycolic acid, polyhydroxybutyrate, poly(alpha hydroxyacids) and polycaprolactone.

B8 34. (Amended) The method of claim 32, wherein the matrix polymer is a polyester co-polymer selected from the group consisting of poly(lactide-co-glycolide), poly(lactic-co-glycolic acid), poly(hydroxybutyrate-hydroxyvalerate) and poly(lactide-co-caprolactone).

BA 36. (Amended) The method of claim 1, wherein in step (a) the W phase is mixed with the O phase in a ratio by volume of 1:100 to 1:1.

Sub D1 37. (Amended) A vaccine delivery system produced by the method of claim 1, wherein the one or more stabilizing agents is/are a polymer selected from the group consisting of poly(vinyl pyrrolidone), poly(vinyl alcohol), polysaccharides, polyethyleneoxide and water soluble proteins, and the method is a Double Emulsion (W/O/X) Solvent Evaporation Technique and in step (b) the stabilized W/O emulsion is dispersed in a liquid phase (X) which is immiscible with the O phase to produce a W/O/X double emulsion comprising W/O droplets from which the solvent is evaporated.

38. (Amended) A vaccine delivery system comprising a plurality of polymer particles, the polymer particles comprising a polymer matrix and a water insoluble protein antigen incorporated with the polymer particles.

Sub D1 BA 45. (Amended) The vaccine delivery system of claim 38, wherein the matrix polymer is a homo- or co-polymer selected from one or more of the group consisting of polyesters, polyanhydrides, polyorthoesters, polycarbonates, polyamides, poly(amino acids), polyacetals, polycyanoacrylates, polyacrylates, biodegradable polyurethanes, non-erodable polyurethanes, polymers of ethylene-vinyl acetate, acyl substituted cellulose acetates, polysaccharides, polystyrenes, polyvinyl chloride, polyvinyl fluoride, poly(vinyl imidazole), chlorosulphonated polyolefins, polyethylene oxide, polyethers and polyoxalates.

46. (Amended) The vaccine delivery system of claim 45, wherein the polymer is a polyester homopolymer selected from the group consisting of polylactic acid, polyglycolic acid, polyhydroxybutyrate, poly(alpha hydroxyacids) and polycaprolactone.

47. (Amended) The vaccine delivery system of claim 45, wherein the matrix polymer is a polyester co-polymer selected from the group consisting of poly(lactide-co-glycolide), poly(lactic-co-glycolic acid), poly(hydroxybutyrate-hydroxyvalerate) and poly(lactide-co-caprolactone).

49. (Amended) The vaccine delivery system of any one of claims 37, 38 and 45-48, wherein the polymer particles have an average diameter of 0.05 - 20 μm according to the volume size distribution.

50. (Amended) A vaccine composition comprising the vaccine delivery system of any one of claims 37, 38 and 45-49.

51. (Amended) A method for the treatment of *Helicobacter* infection in a mammalian host, comprising administering to the mammalian host an effective amount of the vaccine composition according to claim 50.

52. (Amended) A method for preventing or reducing the risk of *Helicobacter* infection in a mammalian host, comprising administering to the mammalian host an effective amount of the vaccine composition according to claim 50.

Cancel claims 39-44.

The following new claims are being added:

53. (New claim) The method of claim 21, wherein the one or more stabilizing agents is/are a polymer selected from the group consisting of poly(vinyl pyrrolidone), poly(vinyl alcohol), polysaccharides, polyethyleneoxide and water soluble proteins.

54. (New claim) The method of claim 21, wherein the one or more stabilizing agents is/are a polar lipid selected from the group consisting of cholesterol, phosphatidylcholine, phosphatidylethanolamine, phosphatidylglycerol, glycolipids and phosphatidic acid.

55. (New claim) The method of claim 21, wherein the one or more stabilizing agents is/are a non-ionic, hydrophobic surfactant selected from the group consisting of sorbitan fatty acid ester, hydrophobic polyoxyethylene alkyl ether, sucrose ester, alkyl-glucopyranoside, polyglycerol polyricinoleate and block-copolymers of ethylene oxide with propyleneoxide and/or lactic acid.

56. (New claim) The method of claim 21, wherein the one or more stabilizing agents is/are an anionic, hydrophobic surfactant selected from an alkylsulphate salt, dialkylsulphosuccinate salt, alkylbenzene sulphonate salt and a fatty acid salt.

57. (New claim) The method of claim 21, wherein the one or more stabilizing agents is/are a cationic, hydrophobic surfactant selected from the group consisting of an alkyltrimethylammonium salt and a dialkyldimethylammonium salt.

58. (New claim) A vaccine composition comprising the vaccine delivery system of claim 49.